

BARIATRIC WEIGHT LOSS CENTER
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June 1, 2005

Dockets Management Branch
5630 Fishers Lane
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RE: Qualified Health Claim (Soy Protein Containing Products and a Reduced Risk of Certain Cancers) (Docket No. 2004Q-0151)

I am a Bariatric Medicine practitioner in New York City and I have a United States Patent No. US 6,413,557 B1 (Texturized Soy Beverage [Whole Soy Milk]) and am writing to submit new information supporting the petition for a qualified health claim linking soy and the prevention of certain cancers and reconfirming the safety of soyfoods for American people's health benefits.

The initial petition submitted in March 2003 by the Solae Company studies linking soy protein and the prevention of breast, prostate and colon cancer. On April 11, 2005, the Soyfood Association of North America wrote to submit new information supporting the petition for the Solae Company.

My patent Texturized Soy Beverage (Whole Soy Milk) contains dietary fibers, phytate, polyphenols, flavors, omega-3 and omega-6 unsaturated essential fatty acids, vitamin-B complex, vitamin-E, calcium, potassium, magnesium, zinc, iron, phosphorus, chromium, selenium, phytochemicals including saponins, and 14.3 g of soy protein per serving. The FDA has suggested the intake of 25g of soy protein as an effective and the palatable consumption level, which is not contained in any other soy beverage on market in any country worldwide. My Texturized Soy Milk has more health benefits than others and therefore has been patented.

The presence of soybeans soluble fiber and phytate that are valuable in slowing to release of glucose into the blood and it has the ability to "smooth out" blood glucose levels, especially following meals (Type 2 Diabetes Mellitus). The soluble fiber in soy may have a specific role in preventing colon cancer. This is a complex issue that involves the production and balance of bacteria in the colon. Mature soybeans contain trace amounts of monosaccharides, such as glucose and arabinose, and

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measurable amounts of di- and oligosaccharides, with sucrose in the range of 2.5-8.2%; raffinose, 0.1-0.9%; and stachyose, 1.4-4.1% (Hymowitz et al. 1972). Although the presence of oligosaccharides in soybeans and soy products is generally considered undesirable in terms of then flatus activity, recent studies have shown some beneficial effects of dietary oligosaccharides in humans (Masai et al.1987, Takasoye et al. 1991, Tomomatsu 1994). These include:

1. Increasing population of indigenous bifidobacteria in colon which, by their antagonistic effect, suppress the activity of putrefactive bacteria,
2. Reducing toxic metabolites and detrimental enzymes,
3. Preventing pathogenic and autogenous diarrhea by the same mechanisms as as described in the reduction of detrimental bacteria,
4. Preventing constipation due to production of high levels of short-chain fatty acids by bifidobacteria,
5. Protecting liver function due to reduction of toxic metabolism,
6. Reducing blood pressure,
7. Having anticancer effects,
8. Producing nutrients such as vitamins, also due to increased activity of bifidobacteria.

Consequently, oligosaccharides have been developed into one of the most popular functional foods components, particularly in Japan (Tomomatsu 1994).

Phytate (inositol hexaphosphate) is present in soybeans in large amounts (Thompson and Erdman 1982, Harland and Obereas 1987). Some animal data suggest phytate may help to lower the risk of colon cancer (Graf and Eaton 1993). Phytate is abundant in high fiber diets, the studies at the University of Maryland explain, at least in part, the epidemiologic observation that high-fiber diets are associated with lower incidence of certain cancer.

The saponins may have potential to reduce blood cholesterol and inhibit the formation of cancer. These phytochemicals may also have a role in weight reduction and an anti-aging effect. In addition, there is a possibility that saponins may interfere with the proliferation of HIV virus, which causes AIDS. The saponin content of soy product is approximately 0.5% on a per weight base (Fenwick and Oakenfull 1981). Saponins from various sources have been shown to have adverse effects in animals, but the saponins in soybeans appear to be relatively weak and not

thought to be of much clinical or nutritional relevance (Ishaaya et al. 1969). Some research indicates saponins may reduce colon cancer risk via their interaction with the intestinal membrane (Sung et al. 1995).

Soy isoflavone have versatile and potent pharmaceutical effects, their actions in the body are well defined. Isoflavones can exert powerful antioxidant effects and have antiangiogenic activity, which means that they interfere with blood vessel growth, an important cancer-fighting property. Isoflavones are known to inhibit enzymes that promote the growth of several types of cancer. In laboratory experiments, isoflavones have been shown to directly suppress the growth of many types of cancers of human and animal origin. The estrogen-moderating effects of soy isoflavones account for their potential benefit in managing symptoms of menopause, premenstrual syndrome, prostate disease, and estrogen- stimulated cancer.

Polyphenols are believed to act at both the initiation and promotion stages of cancer development. They have been reported to interfere with tumor promotion by dampening hormones as described above for plant estrogens. Polyphenols act as "garbage collectors," disposing of cell-damaging mutagens and cancer-causing agents.

The 6th International Tea Science Symposium at Seoul, Korea, 2003 and 2004, results of several epidemiological studies reported that a correlation between green tea intake and a lower risk of esophageal cancer, cancer of oral cavity, gastric cancer and colon cancer. The observed anticancer effects are causally related to the chemical actions of the tea poyphenols. Polyphenols are compounds found in many plants including soybeans, green tea, garlic and grains.

I use the Texturized Soy Beverage (Whole Soy Milk) as meal replacement two times daily for over weight and obese patients, Type 2 diabetes mellitus, hypertension, hyperlipidemia and menopausal symptoms. My patients found delicious and great taste, sense of fullness or satiety and became thirsty and drank increased amounts of water and softens and enlarges the stool and preventing straining.

The results are excellent in reducing the level of blood glucose, especially HgbA1c level, weight reduction, lowering blood pressure, lowering cholesterol, constipation (100%) and menopausal symptoms (hot flushed and sweats (90%), psoriasis, eczema and an anti-aging effect. There has been no complication of hypothyroidism was found since 1997.

In my patent, some examples are contained in mixture of both soy and dairy milk, attempting to offer the advantage of both types of protein in one product. Recently, a combination of two different classes may be used as initial pharmacotherapy when there has been marked hyperglycemia and /or hypertension after meal plan and exercise have failed. I used this combination which you can use both texturized soy milk and texturized soy and dairy milk. The major proteins in milk are casein and whey proteins, which do offer significant health benefits. For example,

lactoferrin, a whey protein, appears to offer a wide spectrum of health benefits, including antibacterial effects, which help prevent infection. Lactoferrin promotes growth, which has implications for human health, particularly for children. I find combinations of whole soy and whey proteins, which do offer significant health benefit in future (In my practice, chronic eczema and silvery scales on bright red in psoriasis patients disappeared and helps kidney functions [proteinuria disappeared] after the consumption of texturized soy beverage after four weeks period).

To eat whole soybeans without liquefying, the whole soybeans will not completely absorb nutrients in the digestive system by chewing. This is due to the fact that most nutrients contain hidden in fiber cell walls.

CONCLUSIONS

A number of phytochemicals in soybeans demonstrate anticarcinogenic activity. The physicochemical properties that affect the functional properties of proteins are related to the three-dimensional structure of proteins. The three-dimensional structure, which is determined by amino acid sequence, is the molecular basis for overall thermodynamic stability, charge distribution, and hydrophobic/hydrophilic properties (Damodaran 1994). Hence, one challenge is to understand the structure-function relationship at molecular levels. This understanding will lead to production of novel protein ingredients by selected modification procedures.

It is apparent that structural modification of soy proteins by enzymatic and chemical methods produce soy protein.

A number of soy protein supplements are widely available but the questioned whether these phytonutrients are as effective as whole soy proteins, which contains saponins, flavors and other nutrients (minerals and vitamins). Therefore, Texturized Soy Beverage (Whole Soy Milk) will to ensure the safety of these products to explore the full potential of soy proteins for food, protein quality and the health benefit.

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Moyard, M.D., M.P.H., Pil F Jenkins Director of Preventive & Alternative
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The United States of America



The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Director of the United States Patent and Trademark Office

Attest



US006413557B1

(12) **United States Patent**
Lee(10) **Patent No.:** **US 6,413,557 B1**(45) **Date of Patent:** **Jul. 2, 2002**(54) **SOY-CONTAINING NUTRITION
SUPPLEMENT AND PROCESS**(76) **Inventor:** **Kyung Ja Lee**, 102-10 66th Rd., Forest
Hills, NY (US) 11375(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 19 days.(21) **Appl. No.:** **09/580,977**(22) **Filed:** **May 30, 2000****Related U.S. Application Data**(63) Continuation-in-part of application No. 08/887,302, filed on
Jul. 2, 1997.(51) **Int. Cl.**⁷ **A61K 35/78**(52) **U.S. Cl.** **424/757; 426/634; 426/507;**
426/508; 426/656(58) **Field of Search** 424/757; 426/634,
426/507, 508, 656(56) **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—Jean C. Witz(74) *Attorney, Agent, or Firm*—Hogan & Hartson LLP(57) **ABSTRACT**A soy-containing nutritional supplement is disclosed which
contains high amounts of soy protein, phytonutrients, and
soluble and insoluble types of fiber.**20 Claims, No Drawings**

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TEXTURIZED SOYMILK "SAPONIN WHITE TM" (U.S. Patent)

Makes One Serving

- ½ Cup of cooked soybeans (one handful raw soybeans-1/4 cup)
- * 1-1 ½ cups of bottle water or 1-1 1/2- cups of Skim Milk add
- 2-4 tablespoons Guava Juice (Nectar)
- or 1/3 Banana (medium size)
- add 1 teaspoon Honey (or Sweet'n low)
- In the evening (before 7:00 PM): 1-1 ½ cups Skim milk and boil add 1-2 Scoops Fat free Sorbet (your favor flavor)

"For Diabetic Patient"

- * 1 ½ -2 cups of bottle water or 1 ½ -2 cups Skim Milk add
- Vanilla extract & 1/4 Banana (medium size) or ½ baby banana
- or 1-2 tablespoons Guava concentration (Nectar)
- or 1/3 Mango (seed & skin off) and ½-1 slice of Papaya
- or Sugar & Fat free Vanilla Sorbet or add ½ teaspoon Instant Caffeine Free Coffee
- Add 1 teaspoon Honey or Sweet'n low.

Directions:

Allow the soybeans to soak in the pot in over night in the refrigerator. In the morning, pour out the water. Rising soaked soybeans under fresh cold tap water and drain. Leave ½ or one inches of water above the soybeans in the pot, and cover the pot. Under a medium heat, allow them to cook until you notice the water reaching the lid. A layer of foam will form on the top of the water (5-6 min.). *It would be easier to see, if you use a clear glass cover.* Turn the heat off. **DO NOT uncover**, Wait 2-3 minutes before doing so. Drain and Pat dry the soybeans with soybeans hulls. Pour the water or skim milk, honey, favor flavor and soybeans and **soybean hulls** into blender and liquefy (more than 7 min.).

Pour into champagne glass or wine crystal glass and drink slowly ENJOY!!!



Health-Related Effects of Green Tea Extract with a Special Focus on Its Effects in Weight Reduction

Tankred Wegener

Consulting Herbal Medicinal Products, Rheda-Wiedenbrueck, Germany.

Most of the scientific evidence for the health benefits of tea consumption has been accumulated over the past decennia. Many of the published studies focus on the tea polyphenols as the principal and most active health-promoting ingredients in green tea. The identified and meanwhile well known substances of green tea – as well as of black and oolong teas – protect lipids from oxidative damage or degradation, have antibacterial and antiviral action, protect skin from UV damage, are anticarcinogenic and antimutagenic, and may have other beneficial effects as well. However, many of these data were obtained in animal and cell culture models. Only few epidemiological and clinical studies have been performed and published (9).

By far the most interest is in the area of anticancer effects, which might be shown by un-numerous papers documenting an intensive and worldwide research. Results of several epidemiological studies – performed in North-East-Asia - are very promising. There documented a correlation between green tea intake and a lower risk of esophageal cancer, cancer of oral cavity, gastric cancer, and colon cancer. These clinical data are supported by countless papers of in vitro and vivo studies. The observed anticancer-effects are causally related to the chemical actions of the tea polyphenols (8,9,12,14).

In the industrialized nations, besides cancer diseases, coronary heart disease (CHD) is the second threatening to human being. From physiological and nutritional points of view, the risks increase with lipids intake, lack of daily exercise and the persons with hypertension and obesity. Accepted and suggested targets for therapeutic approaches are the reduction of body fat and obesity, the lowering of serum and tissue lipids and the reduction of hypertension by pharmacological means. Physiologically, patients are asked to change their diet – this means, to reduce the intake of fat, and to start with exercise and movement. However, as shown by epidemiological studies, these changes in lifestyle are difficult to achieve because patients' compliance is low.

In a time of increasing interest on public health and the desire to improve quality of life, more and more people are conscious of the health hazards of obesity. This change in perception of excess body fat from a "cosmetic" to a "health" issue is encouraging since it is now acknowledged by physicians that even a modest degree of excess fat could increase the risks of complications. It is associated, besides coronary heart disease, with more severe obesity, type II diabetes, hypertension, as well as certain forms of cancer. Additionally, there might arise severe psycho-social problems which interfere with the daily life.

The standard methods for managing body weight by dietary restriction and/or exercise have been proven largely unsuccessful. This is mainly due to the fact that only few people are compliant with a changed dietary regime or exercise therapy. The result is generally only a transient phase of weight loss (or weight stability) followed by a return along the path to an obese condition within a short period of time. These failures of